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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,533

12/13/2005

Anna Fernandez Serrat

3378-0101

6463

6449

7590

10/28/2010

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

JARRELL, NOBLE E

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

10/28/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,533	<b>Applicant(s)</b> FERNANDEZ SERRAT ET AL.	
	<b>Examiner</b> NOBLE JARRELL	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-14, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 47 is/are allowed.
- 6) ☒ Claim(s) 12, 14 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Response to Amendment*

1. Claims 12, 13, 14, 46, and 47 are pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 12, 14, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kundu et al. (*Combinatorial Chemistry and High Throughput Screening*, **2002**, 5, pages 545-550, cited previously).

### ***Determining the scope and contents of the prior art***

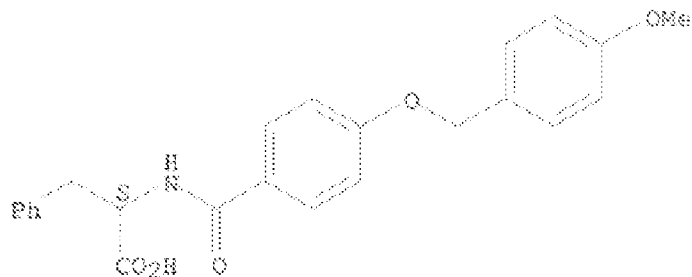
Kundu describes compounds 38 and 39 (page 546), shown below for applicants' convenience. In these compounds, the following definitions apply: variable A is ORI where RI is H; variable W is NH-CH(benzyl); and variable Z is CH<sub>2</sub>-[4-(methoxy or bromo)-phenylene]. Pharmaceutical compositions comprising these compounds are described (page 548, "Biological Activity" section). These compounds are being used  $\alpha$ -Glucosidase inhibitors, which are related to antidiabetic activity, blocking of viral infections and tumor growth (title, page 545, first paragraph of "Introduction" section, page 545).

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RM 524048-71-3 CAPLUS

CN L-Phenylalanine, N-[4-[(4-methoxyphenyl)methoxy]benzoyl]- (CA INDEX NAME)

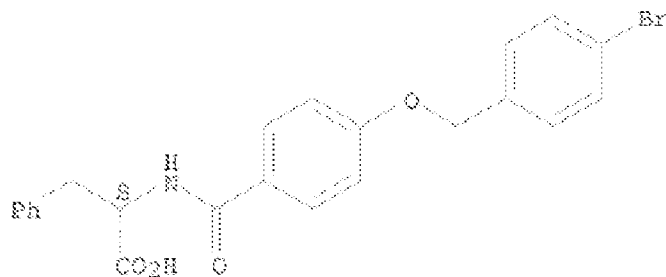
Absolute stereochemistry.



RM 524048-72-4 CAPLUS

CN L-Phenylalanine, N-[4-[(4-bromophenyl)methoxy]benzoyl]- (CA INDEX NAME)

Absolute stereochemistry.

**Ascertaining the differences between the prior art and the claims at issue**

In the prior art, variable I of variable W is an unsubstituted phenyl ring. In the instant application, variable I of variable W is an unsubstituted phenyl ring.

**Resolving the level of ordinary skill in the pertinent art**

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position (relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in preparation of compounds of the elected group).

**Considering objective evidence present in the application indicating obviousness or nonobviousness**

*In re Lohr and Spurlin* (137 USPQ 548) teaches:

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When a new compound so closely related to a prior art compound as to be structurally obvious is sought to be patented based on the alleged greater effectiveness of the new compound for the same purpose as the old compound, clear and convincing evidence of substantially greater effectiveness is needed. Here there are no new properties, but merely an alleged improvement in the same property for use against the same pests.

It is stated by applicants that peroxisome proliferator activated receptors (PPARs) are new pharmacological targets for the development of useful therapeutic agents for the prevention or treatment of diabetes (page 2, lines 8-13). In the application of *Lohr* to a comparison between the prior art and the instant application, it is observed that same disease (diabetes) can be treated through different receptors ( $\alpha$ -Glucosidase in the prior art and PPAR in the instant application). The pending claims of the instant application are compound claims, not method claims. Compound 38 is different from a compound of claims 12, 14, and 46 due to the presence of an unsubstituted phenyl ring for variable I. Substitution of H for a methyl group is obvious when an overlapping disease is present. A 4-methoxy group (attached to variable I') renders a (C<sub>2</sub>-C<sub>4</sub>)-alkoxyl group obvious because diabetes can be treated through modulation of both of these receptors and the structural similarity between the compounds. It shows that the alkoxy substituent present is not critical to a compound of the instant application being effective. Compound 39 is similar to compound 38 except that variable I' is 4-bromophenyl. A bromine substituent belongs to the same periodic family as F or Cl. Consequently, substitution of bromo for F or Cl is obvious in view of the structural similarity, same disease being treated, and the elements of the halogen family. Similar to the alkoxy group, the substitution of one halogen is not critical in view of the prior art. This rejection is maintained for the reasons set forth above.

#### ***Allowable Subject Matter***

5. Claims 13 and 47 appear free of the prior art of record.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 8:30 A.M - 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/

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Primary Examiner, Art Unit 1624